

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

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DePuy Mitek, Inc.	)	
a Massachusetts Corporation	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 04-12457 PBS
	)	
Arthrex, Inc.	)	LEAVE TO FILE GRANTED ON:
	)	AUGUST 28, 2006
a Delaware Corporation	)	
	)	
Defendant.	)	
_____	)	

**SUBSTITUTE DEFENDANTS ARTHREX, INC.'S AND PEARSALLS, LTD.'S**  
**OPENING BRIEF ON CLAIM CONSTRUCTION**

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## I. INTRODUCTION

This is a patent infringement action involving U.S. Patent No. 5,314,446 (“the ‘446 patent”). Plaintiff DePuy Mitek, Inc. (“DePuy Mitek”) is alleging that defendants Arthrex, Inc. (“Arthrex”) and Pearsalls, Limited (“Pearsalls”) (together, “defendants”) infringe various claims of the ‘446 patent<sup>1</sup> by their respective activities in connection with FiberWire® surgical suture.

In *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996), the Supreme Court held that the meaning of patent terms is a matter of law for the Court to decide. Accordingly, pursuant to *Markman* and to the Court’s Order, dated June 19, 2006, entered in this case, defendants submit this opening brief on claim construction explaining their position as to the interpretation of the claim terms at issue in this litigation.

## II. STATEMENT OF FACTS

Arthrex’s accused FiberWire® suture is the first high-strength suture to be introduced in the marketplace. Ex. 1 at 146:7-14. In fact, when it was first introduced in 2001, FiberWire was more than twice as strong as the conventional sutures on the market. Ex. 2 at 8. FiberWire attributes its high-strength to ultra high molecular weight polyethylene (“UHMWPE”), one of the strongest synthetic materials that has ever been created. Ex. 3 at § 1. The UHMWPE is braided together with a polyester known as PET.

The ‘446 patent, to the contrary, does not mention a high-strength suture as being one of the goals of the invention. Rather, the ‘446 patent recognizes that some suture strength will be sacrificed. Ex. 4 at col. 2, ll. 31-37; col. 2, l. 66. The ‘446 patent specification recognizes that there is a tradeoff between suture strength on the one hand and pliability on the other. Ex. 4 at col. 2, ll. 22-28. The ‘446 patent opts to concentrate on pliability and handleability improvement, stating that the goal is to improve pliability and handleability without appreciably

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<sup>1</sup> The asserted claims of the ‘446 patent are claims 1, 2, 8, 9 and 12.

sacrificing its physical properties, such as physical strength or knot security. Ex. 4 at col. 2, ll. 31-37; col. 2, l. 66. This was also confirmed by Dr. Steckel, one of the inventors of the ‘446 patent. Dr. Steckel stated that the goal was to produce a suture which maintained the strength of Ethibond (an existing suture made of PET), while having the feel and pliability of silk, a substance known to be very pliable and easy to use. Ex. 5 at 103:23-104:17. Whereas the goal of the inventors was to *maintain* the strength of Ethibond, with the acknowledgement that some sacrifice in physical strength may be necessary, FiberWire is the exact opposite. FiberWire makes no sacrifice of physical strength – to the contrary, FiberWire provides superior strength as compared with Ethibond. Ex. 2 at 8.

In February 1992, Ethicon filed the patent application that eventually became the ‘446 patent.

### **III. THE ‘446 PATENT AND PROSECUTION HISTORY**

The specification begins with a summary of prior suture development, explaining that multi-filament braided sutures were developed to improve suture pliability compared to monofilament, unbraided sutures. Ex. 4 at col. 1, ll. 5-25. The specification cautioned, however, that mechanisms, *such as coating*, will adversely affect braid mobility. The specification explains that “the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid.” Ex. 4 at col. 1, ll. 26-29. The first example presented is coating, which “improve[s] handling properties,” but at the expense of braid pliability. Ex. 4 at col. 1, ll. 29-31.

The specification explains that the past attempts in the prior art “have overlooked the importance of fiber-fiber friction and its impact of fiber mobility and braid pliability.” Ex. 4 at col. 2, ll. 14-17. The specification suggests that while a braid made entirely of “highly lubricious polymers” can be used to make a highly pliable braid, such a braid “will be relatively weak and

unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.” Ex. 4 at col. 2, ll. 22-28. This theme that lubricious polymers are too weak for suture usage is repeated when the specification explains that a “volume fraction of lubricating yarns . . . above 80% may adversely affect the overall strength of the braid.” Ex. 4 at col. 4, ll. 50-54.

The specification then explains that the proposed solution is to have a suture comprised of a heterogeneous braid made of two different fiber forming materials which exhibits “improved pliability<sup>2</sup> and handling properties<sup>3</sup> . . . without appreciably sacrificing” [the suture’s] physical properties,” (Ex. 4 at col. 2, lines 31-37), namely its “physical strength and knot security.” Ex. 4 at col. 2, l. 66. This proposed solution is repeated throughout the specification. Ex. 4 at col. 2, ll. 62-66; col. 6, ll. 7-8.

The ‘446 patent relies heavily on what is called the “rule of mixtures” to attempt to demonstrate that this combination is an improvement in the art. Ex. 4 at col. 8, ll. 22, 35 and 38. The point made by the inventors is that gains in pliability and handleability by using the combination of highly pliable and lubricious, but relatively weak, materials with a stronger material outweighs the loss of suture strength.

The specification also discusses the use of coating. It explains that coating, if desired, can be added “to further improve the handleability and knot tiedown performance of the braid. It also explains that if the braid “possesses a significant [amount] of the lubricious yarns, the conventional coating may be eliminated saving expense as well as the associated braid stiffening.” Ex. 4 at col. 6, ll. 5-17.

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<sup>2</sup> The ‘446 patent specifically refers to “pliability” in connection with “resistance to bending,” (Ex.4 at col. 1, ll., 11-15, 24) and “bending rigidity,” (Ex. 4 at col. 6, ll. 44-45, col. 8, Table, ll. 44-46), which are the inverse of pliability.

<sup>3</sup> One handling property specifically identified in the patent is “knot tie down.” Ex. 4 at col. 6, ll. 7-8.

In short, the specification teaches several things. First, highly pliable and lubricious yarns are too weak to use alone; that is, the suture would break. Second, using two different materials braided together is designed to improve the handleability and pliability aspects of a suture without significantly hurting the overall braid strength. Third, while adding coating to a braid is helpful for knot tie down and other handleability characteristics, it creates problems with pliability as well as added costs. The use of coating can be avoided, and the downsides it brings can be eliminated if a sufficient amount of the lubricious material is used.

Seven polymers (PTFE, FEP, PFA, PVDF, PETFE, PP and PE) are identified as the yarns that are included for lubricity so as to improve the overall pliability of the braid. Ex. 4 at col. 4, ll. 11-27. Three materials, PET, nylon and aramid, are identified as the ones that could be used for improving the strength of the braid. Ex. 4 at col. 4, ll. 35-40. Notably, the term PE is never associated with the “strength” yarns. This dichotomy, between lubricious polymers for improving overall pliability and polymers added for improving the strength of the braid, is carried into the claims.

Claim 1 of the ‘446 patent is to a surgical suture “consisting essentially of” a heterogeneous braid of a first and second set of yarns in a sterilized and braided construction. Claim 1 further defines the first set of yarns as one of PTFE, FEP, PFA, PVDF, PETFE, PP and PE – the same materials identified in the specification as being pliable and lubricious. The claim defines the second set of yarns as one of PET, nylon and aramid – the same materials identified in the specification as being added for improving the strength of the braid.<sup>4</sup>

As the application for the ‘446 patent was originally filed, there were two sets of claims – one set for heterogeneous braids and a second set for surgical sutures made from

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<sup>4</sup> Since the other asserted claims ultimately are dependent on claim 1 – that is, they have every limitation of claim 1 plus additional limitations – they include the limitations discussed above.

heterogeneous braids. Ex. 6 at 18-20. Early on, Ethicon was required to elect which set of claims it wanted to prosecute. The election was required because the patent examiner observed that they were distinct sets of claims where one set – the heterogeneous braid claims – were an intermediate product that could be used to make surgical sutures (the second set of claims) as well as other products. Ex. 7 at 2. Ethicon elected to pursue the surgical suture claims. Ex. 7. As originally filed, the first suture claim was very broad. It required only that the sterilized suture be comprised of two dissimilar yarns in direct intertwining contact. The specific materials were not part of the claim and it did not include the “consisting essentially of” limitation. Ex. 6 at 18-20.

In the first Office Action, the examiner rejected the suture claims based on U.K. patent application no. 2,218312A to Burgess (“the Burgess application”) (Ex. 8). The Burgess application disclosed a fishing line made of a heterogeneous braid where the braid was made of UHMWPE<sup>5</sup> and either nylon or polyester. Ex. 8. The examiner rejected the suture claims, explaining that the requirements for fishing line were similar to those of suture. Ex. 7 at 4.

In distinguishing the ‘446 patent from the Burgess application, Ethicon responded that because of its braided construction, “the fishing line of Burgess would have poor knot strength properties.” [Emphasis in original.] Ethicon explained that the Burgess braid combination would have poor knot strength properties because it included UHMWPE. Ethicon stated that UHMWPE “gives the line minimal stretchability.” [Emphasis in original.] Ex. 9 at 2. Ethicon further explained that “although this thread has great strength properties, it suffers from low elongation and, in turn, poor knot strength properties.” [Emphasis in original.] Ethicon concluded that, as a result of the different requirements of fishing line and suture, one should not look to the fishing line art. But Ethicon went a step further. Ethicon also told the Patent Office

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<sup>5</sup> The Burgess application uses the term high tensile polythene, the European term for UHMWPE.



that “[e]ven if one were to look to the fishing line art [the UHMWPE/polyester or nylon combination – the fishing line are presented by the Burgess application], one would inevitably design an unacceptable suture.” Ex. 9 at 3-4. In other words, Ethicon argued that the braid combination disclosed in Burgess – UHMWPE and polyester or nylon – was not an acceptable combination for a suture. Ethicon argued that it was not acceptable because the attributes of UHMWPE were not what one would want in a suture, a position that was crucial in overcoming the examiner’s rejection.

Later during prosecution, Ethicon made two pertinent amendments to the claims. First, it abandoned the broad claims that required only that that braid be made of two dissimilar materials. Ex. 10 at 1. The allowed claims were limited to what is known as “Markush groups,” where the dissimilar materials had to be from the group of specifically-named materials.<sup>6</sup> In the allowed claims, the first set of yarns were from a group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE. The second set of yarns were from the group consisting of PET, nylon and aramid. Ex. 10 at 1.

Second, the preamble of the claims was amended to change the term “comprising” to “consisting essentially of.” Ex. 10 at 1. This amendment served to significantly narrow the claims. “Comprising” is an open term; infringement is shown as long as the accused device has every limitation of the claims; infringement is not avoided if the accused device has other additional materials. *See, e.g., Free Motion Fitness, Inc. v. Cybex Intern, Inc.*, 423 F.3d 1343, 1353 (Fed. Cir. 2005). “Consisting essentially of” is not an open term. Infringement is avoided if the accused device contains additional ingredients that materially affect the basic and novel characteristics of the claimed invention. *AK Steel Corp. v. Sollac and Ugine*, 344 F.3d 1234, 1239 (Fed. Cir. 2003).

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<sup>6</sup> A Markush group is one in which the substances grouped are related in some way. *See, e.g.* Manual of Patent Examining Procedure at § 2173.05(h).

#### IV. LEGAL STANDARDS FOR CLAIM CONSTRUCTION

In a patent infringement case, the court has the “power and obligation to construe as a matter of law the meaning of language used in the patent claim.” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), *aff’d*, 517 U.S. 370 (1996). In affirming this decision, the Supreme Court held “that the construction of a patent, including terms of art within its claims, is exclusively within the province of the court.” *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996). “As a general rule, patent claims must be interpreted to sustain their validity if possible.” *Quantum Corp. v. Rodime PLC*, 65 F.3d 1577, 1584 (Fed. Cir. 1995).

The scope of any patent’s protection is defined by its patent claims. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc). The first step in any infringement analysis is to determine a patent claims’ meaning and scope. *Markman*, 52 F.3d at 976-977.

In *Phillips*, the *en banc* Federal Circuit endorsed the uncontroversial maxim that the words of a claim are generally given their ordinary and customary meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention. *Phillips*, 415 F.3d at 1313. The court, however, heard the case *en banc* to resolve a dispute regarding two competing methodologies on how to accomplish the task. In its decision, the Federal Circuit endorsed the approach that started the claim construction analysis with the intrinsic evidence - the claims, the written specification and, if appropriate, the prosecution history - rather than the approach enunciated in *Texas Digital Systems, Inc. v. Telegenix, Inc.*, 308 F.2d 1193 (Fed. Cir. 2002), which began the analysis with dictionary definitions and only permitted consideration of the specification and prosecution history for a limited purpose.

In *Phillips*, the *en banc* Federal Circuit emphasized that a disputed claim term can never be viewed in a vacuum, but rather must always be interpreted in the context of the written description and the prosecution history. *Phillips*, 415 F.3d at 1313. The court reiterated its prior

holding from *Vitronics Corp v. Conceptronic, Inc.*, 90 F.3d 1576 (Fed. Cir. 1996), that “the specification is always highly relevant to the claim construction analysis . . . and that it is the single best guide to the meaning of a disputed term.” *Id.* at 1582. The court also stressed the public notice function of patents. It cautioned that undue reliance on extrinsic evidence poses the risk that it will be used to change the meaning of claims in derogation of “the indisputable public records consisting of the claims, the specification and the prosecution history.” *Phillips*, 415 F.3d at 1319. After discussing the statutory basis for the specification’s importance, the Federal Circuit concluded:

Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.

*Phillips*, 415 F.3d at 1316, quoting *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998).

The Federal Circuit approved the use of the prosecution history, also part of the intrinsic evidence, in the claim construction analysis. The court observed that the prosecution history can provide evidence of how the PTO and the inventor understood the patent and that like the specification, the prosecution history was created by the patentee in attempting to explain and obtain the patent. *Phillips*, 415 F.3d at 1317.

While the Federal Circuit held that extrinsic evidence, including expert and inventor testimony, dictionaries, and learned treatises, could be used, the court also held that such evidence “is ‘less significant than the intrinsic record in determining the legally operative meaning of claim language.’” *Id.* at 1317 quoting *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388

F.3d 858, 862 (Fed. Cir. 2004), quoting *Vanderlande Indus. Nederland BV v. Int’l Trade Comm’n*, 366 F.3d 1316, 1318 (Fed. Cir. 2004).<sup>7</sup>

The Federal Circuit was critical of the *Texas Digital* approach and was particularly cautious about the use of dictionary definitions, stating that “[h]eavy reliance on the dictionary divorced from the intrinsic evidence risks transforming the meaning of the claim term . . . into the meaning of the term in the abstract” and out of its proper context. *Id.* at 1321. The use of dictionary definitions can be troublesome because the applicant “did not create the dictionary to describe the invention” and thus, “there may be a disconnect between the patentee’s responsibility to describe and claim his invention, and the dictionary editors’ objective of aggregating all possible definitions for particular words.” *Id.* at 1321.

Unlike the phrase “comprising,” the phrase “consisting essentially of” in a patent claim is not an open term. Infringement is avoided if the accused device contains additional ingredients that materially affect the basic and novel characteristics of the claimed invention. *AK Steel Corp. v. Sollac and Ugine*, 344 F.3d 1234, 1239 (Fed. Cir. 2003). To determine the basic and novel characteristics, one need look no further than the patent specification. *Id.*

## **V. INTERPRETATION OF DISPUTED CLAIM TERMS**

DePuy Mitek asserts infringement of independent claim 1 and dependent claims 2, 8, 9 and 12. Claim 1 is as follows:

1. A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a

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<sup>7</sup> The court explained that there were several reasons why extrinsic evidence was less reliable than intrinsic evidence. Among other things, it does not have the virtue of being created at the time of prosecution for the purpose of explaining the patent’s scope and meaning, such evidence may not be written for a person of ordinary skill, it can be biased because it is created at the time of and for the purpose of litigation, extrinsic evidence is boundless and each party in litigation will naturally choose the evidence most favorable to its cause and extrinsic evidence poses that it will be used to change the meaning expressed in the public record and thus undermine the public notice function of patents. *Phillips*, 415 F.3d at 1319.

sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and

c) optionally a core.

The parties submit for the Court's construction the two disputed terms which appear in all of the asserted claims of the '446 patent.<sup>8</sup> These two terms, highlighted above, are "PE" and "consisting essentially of," including an identity of the "basic and novel characteristics of the claimed invention."<sup>9</sup>

A. "PE"

Claim Term	Construction
PE	General purpose polyethylene.

One of the principal issues in this case is whether the term PE, as it appears in the asserted claims of the '446 patent, includes UHMWPE, the specialized polymer that provides FiberWire® suture with its superior strength. It should come as no surprise that DePuy Mitek seeks to have the term "PE" construed such that it includes UHMWPE. As we show below, DePuy Mitek can come to that conclusion by relying almost exclusively on dictionary definitions

<sup>8</sup> Since the terms appear in the independent claim, they are also part of the dependent claims because a dependent claim includes all the limitations of the independent claim plus additional limitations. *See, e.g. Robotic Vision Sys., Inc. v. View Engineering, Inc.*, 189 F.3d 1370, 1376 (Fed. Cir. 1999).

<sup>9</sup> The parties agree on the construction of the other two claim terms requiring construction. Specifically, the parties agree that the term "direct intertwining contact," means "the mechanical interlocking or weaving of the individual yarns that make up the suture braid." The parties also agree that the term "volume fraction of the first set of yarns in the braided sheath and core" means "the ratio of the cross-sectional area of the first set of yarns in the sheath and core to the total cross-sectional area of all the yarns in the surgical suture."

and by essentially ignoring the specification and prosecution history of the '446 patent, the same approach rejected by the *en banc* Federal Circuit in *Phillips*.

Defendants, on the other hand, believe the term "PE" in the claims refers to general purpose PE which excludes UHMWPE. As explained below, a proper review of the specification and prosecution history -- the precise approach endorsed by the Federal Circuit in *Phillips*, 415 F.3d at 1313 -- leaves no doubt that the applicants did not believe that UHMWPE is a material that falls within its invention and the meaning of the term "PE."

PE is one of the seven polymers listed in the first set of yarns of claim 1. The specification describes these same seven polymers as "lubricating yarns to improve the overall pliability" of the braid. Ex. 4 at col. 4, ll. 11-27. This theme is repeated throughout the specification. The specification unambiguously states that a braid made solely of "highly lubricious yarns" will result in "a highly pliable braid." Ex. 4 at col. 2, ll. 22-24. Likewise, the examples given in the patent demonstrate that a lubricious yarn is highly pliable and adds more pliability to the braid than expected. Ex. 4 at col. 7, ll. 26-35, 54-64; col. 8, ll. 36-49.

This pliability description is the polar opposite of UHMWPE. The evidence in this case indisputably establishes that UHMWPE is stiff and *not* pliable. DePuy Mitek's own expert, Dr. Brookstein, acknowledged this fact in his report. Ex. 11 at ¶ 56. The stated purpose in the patent is for the first set of yarns (including "PE") to provide improved pliability. It simply makes no sense to construe the term "PE" to include a product that makes the suture too stiff -- the exact *opposite* effect as that described in the patent.

But there is much more. The specification teaches that while a braid made entirely of lubricious materials (such as the materials in the first group) would make a highly pliable braid, such a braid "will be relatively weak and unusable." Ex. 4 at col. 2, ll. 22-25. This is why the specification teaches that there is a tradeoff between braid strength and pliability -- the lubricious

materials have good pliability, but poor braid strength. The notion that the lubricious polymers are too weak for suture usage is repeated when the specification cautions against using more than about 80% of the lubricious yarns because such usage “may adversely affect the overall strength of the braid.” Ex. 4 at col. 4, ll. 50-54.

The description of the first and second groups of yarns continues this theme. The specification teaches that a yarn from the second group of yarns needs to be added “to provide improved strength to the heterogeneous braid.” Ex. 4 at col. 4, ll. 33-36. The reason that a “strength” yarn is needed is obvious -- the “pliable” yarns of the first set are too weak, just as the specification teaches. Ex. 4 at col. 2, ll. 22-25; col. 4, ll. 52-54.<sup>10</sup>

Once again, it would make no sense to include UHMWPE within the meaning of “PE. Unlike general purpose PE, UHMWPE is an incredibly strong material, one of the strongest materials known to man. It simply is not the kind of material which must be balanced against strong materials to achieve an acceptable suture. It simply makes no sense to include such a strong material where the patent teaches the exact opposite.

Notably, while PE is included in the group of seven lubricious materials identified for improving pliability, PE is *not* included in the group of materials identified for strength. Nor is the term PE ever associated with the “strength” yarns in the specification of the ‘446 patent. If PE included UHMWPE, one would have expected to see “PE” appear in the strength list. At a bare minimum, one would have expected to see *some* mention in the patent the “PE” could also

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<sup>10</sup> That the ‘446 patent considers the lubricous materials to be relatively weak is also confirmed by the tests described in the specification. For example, the Table depicts results for a multifilament braid made entirely (*i.e.*, 100 %) of a lubricious first fiber-forming material (*i.e.* CONTROL II made up of 100% PTFE). This braid was the weakest of the four braids tested, which is entirely consistent with the teachings of the specification.

Moreover, the ‘446 patent relies heavily on what it calls the “rule of mixtures” to explain that gains in pliability and handleability by using the combination of lubricious, but relatively weak materials (*i.e.* the seven lubricious polymers) with a stronger material (*i.e.*, the three strength materials) outweighs the loss of suture strength realized due to the lubricious materials.

impart strength. This is particularly true in light of the fact that Ethicon and the inventors knew that UHMWPE has great strength. Inventor Steckel testified that he knew during the development work that lead to the '446 patent that UHMWPE had great strength. Ex. 5 at 190:12-191:3. Likewise, when responding to an office action during prosecution, Ethicon acknowledged that UHMWPE "has great strength properties." Ex. 9 at 2. There is a plain and simple reason that there is absolutely no mention of "PE" having strength; UHMWPE was the furthest thing from the applicants' minds when they described their invention.

As the Federal Circuit has instructed on several occasions, [t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction; *Phillips*, 415 F.3d at 1316; *Renishaw*, 158 F.3d at 1250. Here, the interpretation of "PE" that naturally aligns with the patent's description of the invention is general purpose PE and *not* UHMWPE.

If there were any doubt – and there is none – it is categorically removed by a review of Ethicon's arguments against UHMWPE in the prosecution history, which is part of the intrinsic evidence that should be consulted in determining the meaning of claim terms.

As mentioned above, during prosecution of the '446 patent, the examiner rejected the suture claims based on the Burgess application, which disclosed a fishing line made of a heterogeneous braid where the braid was made of UHMWPE and either nylon or polyester. Ethicon argued the Burgess braid would make a poor suture. In particular, the combination would be poor *because it contained UHMWPE*, a product with "minimal stretchability" and which "suffers from poor elongation." Ex. 9 at 2-3. Ethicon concluded by stating that "[e]ven if one were to look to the fishing line art, *one would inevitably design an unacceptable suture.*" Ex. 9 at 3-4. [Emphasis added.] In other words, Ethicon told the patent examiner, and by extension the public, that the combination disclosed in Burgess – UHMWPE and polyester or



nylon – would *not* make an acceptable suture. And the reason that the combination would be unacceptable was because it contained UHMWPE.

The fact is that UHMPE and general purpose PE are fundamentally very different materials. They are used for different purposes, and one can not be substituted for the other. Ex. 12 at 22. General purpose polyethylene has been around for decades and established itself as a general purpose commodity polymer. Ex. 3 at § 1. Since its introduction in fiber form in 1985, UHMWPE, to the contrary, has been considered a specialized high performance product. Ex. 3 at § 1. General purpose polyethylene and UHMWPE are simply not substitutes for each other. Ex. 12 at 22. Moreover, the key structural characteristics – molecular weight and molecular structure – of UHMWPE are very different than that of general purpose PE. Ex. 3 at § 2. UHMWPE has a molecular weight in the range of 1 to 5 million, whereas general purpose PE has a molecular weight in the range of 50,000 to several hundred thousand. UHMWPE also exhibits a much higher degree of crystalline orientation and crystalline content as compared with general purpose PE. These stark differences in molecular structure are the basis for UHMWPE's superior strength characteristics. Ex. 3 at § 2.

Despite all of the above, and contrary to the clear teachings of the '446 patent, DePuy Mitek has asserted that the term "PE" means "all types of polyethylene (PE) including ultra high molecular weight polyethylene." Ex. 11 at ¶ 27; Ex. 13 at ¶ 28.

The only way DePuy Mitek comes to this conclusion is by essentially ignoring the clear teachings of its own specification. DePuy Mitek must ignore the specification since it reveals the truth about what the term PE means in the context of the '446 patent – i.e., that it includes general purpose polyethylene, but does not include UHMWPE. Even DePuy Mitek's own expert initially admitted this. Dr. Hermes' own first impression when reading the '446

patent was that it “seem[ed] to teach away from UHMWPE.” Ex. 14; Ex. 15 at 335:12-336:15. Dr. Hermes’ first impression was entirely correct.

Undaunted by the truth, however, DePuy Mitek forges ahead and seeks to improperly construe the term PE through the use of extrinsic evidence in the form of technical treatises that take the claim terms completely out of the context in which they were written and intended -- the *Texas Digital* approach. As described above, however, this approach was resoundingly rejected by the Federal Circuit in the landmark *Phillips* decision.

The *Phillips* court warned, “[h]eavy reliance on the dictionary divorced from the intrinsic evidence risks transforming the meaning of the claim term . . . into the meaning of the term in the abstract” and out of its proper context. *Id.* at 1321. The court further reasoned that the use of dictionary definitions can be troublesome because the applicant “did not create the dictionary to describe the invention” and thus, “there may be a disconnect between the patentee’s responsibility to describe and claim his invention, and the dictionary editors’ objective of aggregating all possible definitions for particular words.” *Id.* at 1321.

The “disconnect” that troubled the Federal Circuit is the very basis for DePuy Mitek’s claim construction. For example, DePuy Mitek’s expert, Dr. Hermes, points to a technical treatise – entirely divorced from the context of the ‘446 patent – as supporting the assertion that the term “PE,” as it appears in the ‘446 patent, is the generic name for all types of PE, including UHMWPE. The same treatise Dr. Hermes relies upon, however, expresses the very same concerns stated by the *Phillips* court 18 years later. The treatise states that so-called source-based nomenclatures have “serious deficiencies,” and predicts that as a result there will be a gradual shift “away from starting materials and toward the structure of the macromolecules.” Ex. 16 at 193. When confronted with this concern and prediction expressed in the same treatise he relied upon, Dr. Hermes could only state that that was the opinions of the authors and that he

did not have enough knowledge to disagree with those authors. Ex. 15 at 246:25 – 247:19. This is the approach the *Phillips* court warned about.

As made clear by the entirety of the intrinsic evidence – *i.e.*, the specification and the prosecution history – when the inventors used the term “PE,” they intended to mean general purpose polyethylene and not UHMWPE. Even DePuy Mitek’s own expert, on his initial reading of the patent, recognized that the specification “seems to teach away from UHMWPE.” For all the above reasons, Defendants’ proposed construction should be adopted.

B. “Consisting essentially of”

Claim Term	Construction
Consisting essentially of	<p>i) The claimed surgical suture excludes additional ingredients that materially affect the basic and novel characteristics of the claimed invention.</p> <p>ii) The basic and novel characteristics of the claimed invention are a suture having two dissimilar yarns (from the list identified in the claims) braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties.</p>

As described above, it is well settled that the transitional phrase “consisting essentially of,” as it appears in the asserted claims of the ‘446 patent, is construed to mean that infringement is avoided if the accused device contains additional ingredients that materially affect the basic and novel characteristics of the claimed invention. *AK Steel Corp.*, 344 F.3d at 1239. The parties do not appear to dispute this basic principle. The parties do dispute, however, the identity of the “basic and novel characteristics of the claimed invention.” As the Federal Circuit stated in *AK Steel*, one need look no further than the specification in order to make that determination. *Id.* at 1239. This case is no different.

In making this determination, the focus, of course, starts with the claims because the claims define the scope of the protected invention. Here, the claims are not merely to two dissimilar materials braided together,<sup>11</sup> but rather to the two groups with specific materials for each group (PTFE, FEP, PFA, PVDF, PETFE, PP and PE for the first group; PET, nylon and aramid for the second group). Thus, the issue is what does the specification attribute as the basic and novel characteristics for a suture braid made of these specific materials.

Focusing on the purpose of the recited materials, the specification of the '446 patent identifies the basic and novel characteristics of the claimed invention as being a suture having two dissimilar yarns (of the materials claimed) braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties. This concept is repeated throughout the specification, both when referring to the essential idea behind the patent and when discussing the recited materials directly. Ex. 4 at col. 2, ll. 29 – 37; ll. 62 – 66; col. 4, ll. 11-40; col. 6, ll. 7 – 8. Matthew Goodwin, the attorney who prosecuted the application for Ethicon, also confirmed this was the basic aspect of the invention. Ex. 17 at 110:14-20.<sup>12</sup>

As previously mentioned, the specification describes that there is a tradeoff between braid strength and pliability. In the specification, this tradeoff is advantageous because the gains achieved in pliability and handleability outweighs the loss of suture strength resulting from combining a weaker, pliable material with the stronger material. According to the specification,

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<sup>11</sup> As originally filed, the application included a broad claim of two dissimilar fibers braided together without specifying any specific materials. Ex. 6. That broad claim, however, was abandoned during prosecution. Ex. 10 at 1. Language in the patent specification that relates to this broad abandoned claim cannot serve as a basis for determining the basic and novel characteristics of the narrower claims.

<sup>12</sup> This is also consistent with Dr. Steckel's testimony that the goal was to improve the handleability and pliability to make the suture more like silk while maintaining the strength of the existing Ethibond polyester suture. Ex. 5 at 103:23-104:17.

the resulting suture is one with improved handleability and pliability performance without significantly sacrificing its physical properties. Ex. 4 at col. 2, ll. 31-37; col. 2, l. 66.

Improved pliability and handleability on the one hand, with a minimal reduction in strength on the other hand are the characteristics attributed to the specific materials recited in the claims. The first set of yarns is included to improve pliability and surface lubricity. But because such yarns are weak, a strength component is added by a yarn of the second group. Ex. 4 at col. 2, ll. 22-25; col. 4, ll. 11-40.

Accordingly, by reviewing the specification, it becomes evident that the basic and novel characteristics of the claimed invention are a suture having two dissimilar yarns (from the list identified in the claims) braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties. We ask that the Court adopt this construction.

## **VI. CONCLUSION**

For all the foregoing reasons, defendants request that the Court adopt the claim interpretations contained herein.

Dated: August 11, 2006

Respectfully submitted,

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Counsel for Defendants  
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**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that a true and correct copy of the foregoing Substitute Defendants Arthrex, Inc.'s and Pearsalls, Ltd.'s Opening Brief on Claim Construction was served, via the Court's email notification system on the following counsel for Plaintiff on the 29th day of August 2006:

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/s/Salvatore P. Tamburo

# **SUBSTITUTE EXHIBIT 15**



Deposition of:  
Dr. Matthew Hermes, Vol. I

June 27, 2006

Page 1

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS  
C.A. NO. 04-12457 PBS

**COPY**

-----x  
DePUY-MITEK, INC.,

A Massachusetts Corporation,  
Plaintiff,

vs.

ARTHREX, INC.,

A Delaware Corporation,  
Defendants.

-----x  
DEPOSITION OF DR. MATTHEW HERMES

Philadelphia, Pennsylvania

June 27, 2006

Reported by:

CONSTANCE S. KENT, CSR, RPR

JOB NO.: 350

1 clearer source-based names, correct?

2 A. Yes.

3 Q. Okay. Is it your understanding that  
4 this document is designed to try and clear up an  
5 ambiguity that existed?

6 A. No, it's my understanding that it's a  
7 document describing generic source-based  
8 nomenclature.

9 Q. What does it mean to you when it says  
10 it solves these problems and yields clearer  
11 source-based names?

12 A. Whatever problems there were, it's  
13 attempting to clear them up. I'm sorry, I'm not  
14 familiar with what the specific problems were.

15 Q. But you agree with me this document  
16 in 2001 is an attempt to clear up problems that  
17 existed on names?

18 A. That's what it says sir, yes.

19 Q. Let's -- let's go to Exhibit 18 if we  
20 could, please.

21 A. Indeed.

22 Q. Could you turn to page 193 of this  
23 report?

24 A. Yes.

25 Q. Is it correct that this -- this

1 exhibit is saying that there are deficiencies of  
2 source-based nomenclature?

3 A. The -- the paragraph beginning the  
4 principal deficiency talks in general about a  
5 nomenclature problem that has been inherent in  
6 defining the names of polymers, yes.

7 Q. And if you look further down the  
8 paragraph, doesn't it conclude, the paragraph: The  
9 rapid advances now being made in the structural  
10 determination of polymers will gradually shift the  
11 emphasis of polymer nomenclature away from the  
12 starting materials and toward the structure of the  
13 macromolecules?

14 A. That's a -- that is the opinion of  
15 the authors.

16 Q. Do you have any reason to disagree  
17 with the opinions of the authors?

18 A. I don't think I have enough knowledge  
19 to disagree with those authors.

20 Having said that, this was published  
21 in 1987, 20 years ago, and there's no -- there's no  
22 indication in the field of ethylene and polyethylene  
23 that anything of that kind is going on these days.  
24 Polyethylene is still polyethylene, and the -- the  
25 structural details do not appear in the source-based

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July 25, 2006

Page 252

1 UNITED STATES DISTRICT COURT  
2 DISTRICT OF MASSACHUSETTS  
3 C.A. NO. 04-12457 PBS

4 \_\_\_\_\_ x

5 DePUY-MITEK, INC.,

6 A Massachusetts Corporation,

7 Plaintiff,

8 vs.

9 ARTHREX, INC.,

ORIGINAL

10 A Delaware Corporation,

11 Defendants.

12 \_\_\_\_\_ x

13 DAY 2 OF 2

14 CONTINUED VIDEOTAPED DEPOSITION

15 OF DR. MATTHEW HERMES

16 Philadelphia, Pennsylvania

17 July 25, 2006

18

19

20 Reported by:

21

22 PAMELA HARRISON, RMR, CRR, CSR

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24

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Deposition of:  
Dr. Matthew Hermes, Vol. II

July 25, 2006

		Page 335
1	your -- you made them the first time you reviewed	01:01:49p
2	the report, if I understood your answer	01:01:51p
3	correctly?	01:01:53p
4	MR. BONELLA: Object to form.	01:01:54p
5	THE WITNESS: I believe so, but	01:01:55p
6	I'm not certain.	01:02:02p
7	BY MR. SABER:	01:02:05p
8	Q. Okay. I want to ask you about near --	01:02:05p
9	on the bottom there you have numbers one, two,	01:02:09p
10	three, and four?	01:02:11p
11	A. Yes, sir.	01:02:12p
12	Q. I want to ask you about number three,	01:02:12p
13	if I could, please. Could you read the first	01:02:14p
14	sentence there, just to make sure that it's --	01:02:19p
15	A. This is my note, Mr. Saber, is that	01:02:22p
16	right?	01:02:24p
17	Q. Yes, sir.	01:02:24p
18	A. You want me to read my note.	01:02:25p
19	Q. Yes, sir. The first sentence.	01:02:27p
20	A. I'll be glad to.	01:02:28p
21	"'446 -- '446 teachings on	01:02:29p
22	offsetting properties of yarn A with yarn B may	01:02:45p
23	seem to teach away from ultra high molecular --	01:02:50p
24	UHMWPE, but the critical principle is mixing	01:02:57p
25	yarns and getting better than accepted	01:03:04p

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Dr. Matthew Hermes, Vol. II

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		Page 336
1	properties."	01:03:08p
2	Q. When you used the --	01:03:10p
3	A. I'm not finished.	01:03:12p
4	Q. Okay. I'm sorry, sir.	01:03:13p
5	A. It doesn't -- I'm not finished.	01:03:14p
6	"It doesn't LIMIT," in capital	01:03:18p
7	letters, "A, strength, or B, lubricity, just	01:03:20p
8	suggests it."	01:03:27p
9	Q. When you used the nomenclature I think	01:03:27p
10	you said UHMWPE?	01:03:32p
11	A. Yes.	01:03:35p
12	Q. Does that mean ultra high molecular	01:03:35p
13	weight PE?	01:03:37p
14	A. That did mean ultra high molecular	01:03:38p
15	weight polyethylene, yes.	01:03:39p
16	Q. Right. When you wrote at the end, you	01:03:41p
17	said, just suggests it, A, strength, and B,	01:03:46p
18	lubricity, what did you mean by that?	01:03:50p
19	A. I meant -- I meant specifically that	01:03:51p
20	the teachings in the preferred embodiment in	01:03:54p
21	which -- in which the preferred embodiment	01:03:58p
22	mentions the relationship of -- the preferred	01:04:02p
23	embodiment discussing PTFE, that -- in which we	01:04:05p
24	talk about the strength of the braid and the	01:04:11p
25	relationship of strength to the braid, that that	01:04:17p